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Dated: October 15, 2008  
Electronic Signature for Michael H. Teschner: /Michael H. Teschner/

No.: CIMA 3.0-030 CONT CONT  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Pather et al.

Application No.: 09/661,693

Group Art Unit: 1617

Filed: September 14, 2000

Examiner: U. Ramachandran

For: SUBLINGUAL BUCCAL EFFERVESCENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

Pursuant to M.P.E.P. § 2001.06(c), where the subject matter for which a patent is being sought is or has been involved in litigation, the existence of such litigation and any other material information arising therefrom must be brought to the attention of the U.S. Patent and Trademark Office.

Accordingly, applicants hereby provide Notice Letters received from Watson Pharmaceuticals and from the law firm of Sterne Kessler Goldstein Fox, who represent Barr Laboratories, Inc. These letters were sent pursuant to 21 U.S.C. § 355(j)(2)(B) in connection with filings of Abbreviated New Drug Applications in connection with Cephalon's New Drug Application No. 21-947.

Two patents referenced in these letters are listed in *Approved Drug Products With Therapeutic Equivalence Evaluations* ("the Orange Book") in connection with that New Drug Application. However, the above-captioned application contains claims which cover the products and methods subject to the

approved NDA No. 21-947. Accordingly, patents issuing therefrom could be listable in the Orange Book as well. The Notice Letters from the Sterne Kessler firm are provided in their entirety in the manner in which they were received.

The Notice Letter from Watson is marked CONFIDENTIAL. Applicant requested that Watson provide permission to produce the Notice Letter in an unredacted form but Watson denied that request. Accordingly, what is enclosed herewith is a redacted letter provided by Watson's counsel.

Also enclosed are copies of the initial pleadings from lawsuits brought by Cephalon/CIMA against Barr and Watson. Specifically, enclosed please find a copy of the complaint and Barr's answer in Civil Action No. 08-cv-00455(UNA) pending between Cephalon/CIMA and Barr in the U.S. District Court for the District of Delaware. Also enclosed please find the complaint in Civil Action No. 08-cv-00330 between Cephalon/CIMA and Watson also in the U.S. District Court for the District of Delaware. No further pleadings were available to the undersigned at the time of this Information Disclosure Statement. This information is being provided in the following pending applications: 09/661,693 filed 14SE2000; 11/511,098 filed 28AU2006; 11/027,353 filed 30DE2004; 11/026,759 filed 30DE2004; 11/026,132 filed 30DE2004.

It is respectfully requested that the information submitted herewith be made of record and considered with respect to the above-referenced U.S. patent application. Submission of the present Information Disclosure Statement should not be taken as an admission that the cited information or anything referenced therein is legally available prior art or that the same is pertinent or material.

Should the examiner have any questions with regard to the foregoing, the examiner should contact the undersigned at 908.654.5000.

In the event that any fee is due in connection with the present Information Disclosure Statement, the Commissioner is hereby authorized to charge the same to our Deposit Account No. 12-1095.

Dated: October 15, 2008

Respectfully submitted,  
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